DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 5, 2015

XuChang ZhengDe Environstar Medical Products Co., Ltd.
c/o Mr. Mike Gu
Regulatory Affairs Manager
Osmunda Medical Device Consulting Co., Ltd.
7th Floor Jingui Business Building No. 982 Congyun Rd
Baiyun District
Guangzhou, Guangdong
510420 CHINA

Re: K141467
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: February 6, 2015
Received: February 9, 2015

Dear Mr. Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141467

Device Name
Surgical Gown

Indications for Use *(Describe)*
Surgical gowns are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.
Models:
- Standard surgical gown, model number: ZD2514, ZD2515, ZD2517, ZD2519 and ZD2520;
- Reinforced surgical gown, model number: ZD2544, ZD2545, ZD2547, ZD2549 and ZD2550.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

XuChang ZhengDe Environstar Medical Products Co.,Ltd

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Secondary Contact Person:	Chen Ming
	Quality Director
	XuChang ZhengDe Environstar Medical Products Co., Ltd
Date Prepared:	February 26, 2015

II. DEVICE

Name of Device:	Surgical Gown
Common/Usual Name:	Gown, Surgical
Classification Names:	Surgical apparel (21 CFR878.4040)
Regulation Class:	II
Product Code:	FYA

III. PREDICATE DEVICE

Jiangsu Guangda Surgical Gown, Jiangsu Guangda Medical Material Co., Ltd, K121152.

GRI's Surgical Gowns, GRI MEDICAL & ELECTRONIC TECHNOLOGY CO., LTD, K102652.

These predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. It is made of soft, air permeable SMS non-woven fabric.

V. INDICATIONS FOR USE

Surgical gown are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	Predicate Device	Predicate Device	Proposed
K number	K121152	K102652	-
Manufacturer	Jiangsu Guangda Medical Material Co., Ltd.	GRI MEDICAL & ELECTRONIC TECHNOLOGY CO., LTD	XuChang ZhengDe Environstar Medical Products Co., Ltd
Intended Use	Jiangsu Guangda's Reinforced Surgical Gowns, Model Number GD-SG-01, are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	GRI's Non Reinforced, Film Reinforced, and Fabric Reinforced Surgical Gowns are sterile or non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	Surgical gown are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.
Material	SMS	SMS	SMS
Weight per square (g)	45	50	45
Durability	Disposable	Disposable	Disposable
Size	XL	S, M, L, XL, XXL	M-S, M, L, XL, XXL

Color	Blue	Various	Blue
Reinforced area	PE + PP two layer compound protective reinforcement with 100% white Terylene cuffs	polypropylene/polyethylene protective reinforcement	air permeable membrane composite PE+ PP, double barrier non-woven fabric
Style	Reinforced	Reinforced and non reinforced	Reinforced and non reinforced
Hydrostatic pressure: AATCC 127	>20 cm	Met acceptance criteria	>50 cm
Impact penetration: AATCC 42	≤1	Met acceptance criteria	≤1
Biocompatibility	under the conditions of the study, not an irritant; under conditions of the study, not a sensitizer; under the conditions of the study the device is non-cytotoxic.	under the conditions of the study, not an irritant; under conditions of the study, not a sensitizer; under the conditions of the study the device is non-cytotoxic.	under the conditions of the study, not an irritant; under conditions of the study, not a sensitizer; Under the conditions of the study the device is non-cytotoxic.
Tensile strength: ASTM D 5034	Length(lbf): 17.2 Width(lbf): 25.3	Met acceptance criteria	Length(lbf): 17.7 Width(lbf): 25.7

Tearing strength: ASTM D 5733	Length yarns torn(lbf): 4.5 Width yarns torn(lbf): 9.6	Met acceptance criteria	Length yarns torn(lbf): 4.7 Width yarns torn(lbf): 9.8
Seam strength: ASTM D 1683	Armhole seam (lbf) 17.4(F.B.) Shoulder seam (lbf) 9.4(F.B.)	Met acceptance criteria	Armhole seam (lbf) 17.6(F.B.) Shoulder seam (lbf) 9.5(F.B.)
Flammability: 16 CFR Part 1610	Class 1	Met acceptance criteria	Class 1
Sterilization method	EO	EO	EO
Resistance to blood and liguid penetration	Level 4 per AAMI PB70	Level 4 per AAMI PB70	Level 3 per AAMI PB70

The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

Therefore, the subject device is determined as safe and effectiveness.

VII. CONCLUSIONS

XuChang ZhengDe Environstar Medical Products Co.,Ltd considers the Surgical Gown to be as safe, and as effective as the predicate devices. It does not raise any new issues of safety or effectiveness.